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03 NOV -6 P3:16

November 6, 2003

VIA HAND DELIVERY

Steven D. Vaughn, D.V.M.
Director
Office of New Animal Drug Evaluation
c/o Document Control Unit (HFV-199)
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

Re: FDA Form 356V

Dear Dr. Vaughn:

Pursuant to the August 8, 2003 Notice of Opportunity for Hearing (68 Fed. Reg. 47332), we hereby submit FDA Form 356v as reconfirmation of the Agency's prior approval of NADA 141-137, a Bacitracin Methylene Disalicylate product, for the indications and use set out in 21 C.F.R. §§ 558.15(g)(1) and 558.76(d)(1) and (2). Furthermore, pursuant to this same Notice of Opportunity for Hearing, we submit FDA Form 356V as reconfirmation of the Agency's prior approval of NADA 138-939, a neomycin/oxytetracycline combination product, for the indications and use set out in 21 C.F.R. § 558.15(g)(2). We would further note that PennField Oil Company previously submitted a Form 356v to the agency for its Bacitracin Methylene Disalicylate product on November 14, 2002. Accordingly, this present submission is clearly a duplicative and unnecessary one, which is being made to merely satisfy the agency's request and to reconfirm the agency's prior approval of NADA 141-137 for all the indications of use set out in § 558.76.

Respectfully yours,

Edward John Allera

Enclosures

2003N-0324 SUP1

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03 NOV -6 P3:18

November 6, 2003

VIA HAND-DELIVERY

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2003N-0324: Request for Hearing Regarding NADA 141-137 (Pennfield Oil Co.)

To Whom it May Concern:

In accord with 21 C.F.R. §§ Part 12 and C.F.R. § 514.200, please find attached a specific full factual analysis of documents, studies, and other information supporting Pennfield Animal Health's September 8, 2003, request for hearing in response to the Center for Veterinary Medicine's general Notice of Opportunity for Hearing ("NOOH"). The broad language of the NOOH and the failure of the Center to place data and analysis on file make specific paragraph-by-paragraph rebuttal of the Agency's position premature. Pennfield will continue to supplement this record and reserves the right to do so, as CVM responds with relevant documents requested by Pennfield through its Freedom of Information Act and due process requests and as CVM fulfills its disclosure obligations to ensure a complete administrative record. The following provides a concise summary of Pennfield's position regarding the Agency's approval of NADA 141-137, Bacitracin Methylene Disalicylate ("Bacitracin MD").

Specifically, as the Agency knows, Fermenta Animal Health, one of Pennfield's predecessors in interest, is listed as the sponsor of NADA 141-137 Bacitracin MD in § 558.15, which includes the indications for use in § 558.76 by cross-reference. Neither § 558.15 nor § 558.76 limits the indications of use for which Pennfield or its predecessors in interest could market their Bacitracin MD under NADA 141-137. Indeed, not until Alpharma filed suit against the Food Drug Administration this year, did the Agency ever raise an issue regarding the scope of the approved claims available to the sponsor of NADA 141-137. Yet, the Agency now disingenuously states that it may have improperly led companies - over a thirty-year period - to believe that the scope of claims available was broader than those reviewed under DESI. The history of DESI and the documents and meetings that FDA has had with Fermenta's successor in interest, Boehringer Ingelheim Vetmedica, Inc. ("BIV") and Pennfield since 1998 establish otherwise conclusively.

Between 1996 and 1998, BIV, Pennfield's immediate predecessor in interest, had several discussions with FDA regarding the NADA 141-137. In August of 1998, BIV provided FDA with evidence that its Bacitracin MD product was on the market prior to 1969. Pursuant to a letter dated Nov. 17, 1998, BIV certified that Bacitracin MD was approved. This letter indicated that BIV's Bacitracin MD product was approved for use in all major species and for the medications now in dispute. On December 8, 1998, Dr. Don Gable of BIV received a phone call from Dr. McCrae of CVM requesting a copy of the labels to be approved. Dr. Gable faxed those labels to Dr. McCrae immediately. It is clear that Dr. McCrae and CVM understood that those labels represented the claims that BIV believed it was entitled to under the regulations. Under FDA's regulations, 21 C.F.R. § 10.70 and Part 514, CVM is required to maintain all the material in the administrative file for the drug product. On December 17, 1998, with a copy of BIV's current Bacitracin MD labels in the file, Dr. Sundlof sent a letter to BIV informing the company that its Bacitracin MD was approved for the indications of use set forth in its labels provided to the Agency. Moreover, this letter is not the only letter to confirm the approval of NADA 141-137 for the indications of use set out in § 558.76.

On March 12, 2002, BIV sent a letter to the Agency which discussed the impending transfer of ownership of NADA 141-137 from BIV to Pennfield. This letter contains the December 17, 1998 letter, confirming the approved status of BI's NADA 141-137, and the label which CVM relied upon to reconfirm NADA 141-137's approval. It is important to note that CVM never raised any issue regarding the scope of BIV's approval when it subsequently met with BI and Pennfield to discuss several different matters, including the transfer of NADA 141-137 to Pennfield.

On October 3, 2002, CVM once again acknowledged the approval of NADA 141-137 without raising one issue regarding the uses set out in the product labeling. On November 14, 2002, Pennfield submitted a supplemental Form 356v for its bacitracin MD drug product to the Agency. This submission contained the proposed labeling for Pennfield's Bacitracin MD product. On December 23, 2002, CVM once again met with Pennfield regarding NADA 141-137 and, after raising an issue regarding the active pharmaceutical ingredient manufacturer, reaffirmed Pennfield's approval pursuant to §§ 558.15 and 558.76. Thus, there can be no question that the paper record clearly shows that the Agency reaffirmed Pennfield and its predecessor in interest's approval for all the claims set forth in § 558.76. To argue otherwise, calls into question the veracity of the Center and individuals within the Center.

While FDA did not articulate its basis for granting the approval for all the claims set forth in § 558.76, it is not required to do so. The regulations are binding on FDA as well as industry, and Pennfield and its predecessors in interest were entitled to - and did - rely upon them. Presumably, the Agency could have reached this decision under multiple theories. First, the Agency could have concluded that all the claims are effective under its historical interpretation of using all the data generated under the Drug Efficacy and Study Implementation ("DESI") process. Under DESI for antibiotic drugs, the Agency has applied data submitted by individual companies to the industry as a whole. This is particularly true when the data supported an

upgrade in DESI status rather than a unique or novel use of the drug. In this regard, the so-called post-1982 claims approved via § 558.76 could have hardly been considered unique or novel. Indeed, the historical record shows that the so-called post-82 claims were actually covered by the DESI review uses that existed prior to 1982. These more refined claims were subsumed within these DESI claims, and the materials supporting this conclusion are enclosed.

The Agency could have also concluded in 1998, that the claims on the BIV label were approvable pursuant to the Generic Animal Drug and Patent Restoration Act ("GADPTRA"). In this regard, there is no doubt that FDA could use efficacy data that was previously submitted to support its approval. Moreover, the Agency has waived the bioavailability requirements when it believed that the products were functionally equivalent.

Accordingly, regardless of how the Agency arrived at its decision, the documentary evidence, included in today's submission, clearly establishes that FDA approved NADA 141-137 for all the indications of use set forth in § 558.76 and that this decision is consistent with the DESI review process and GADPTRA.

Respectfully yours,

Edward John Allera

Enclosures: as stated

Declaration of Donald A. Gable, DVM
In Support of Pennfield Oil Company/Pennfield Animal Health's
Request for Hearing re: NADA 141-137 (Bacitracin Methylene Disalicylate)

Docket No. 2003N-0324

1. My name is Donald A. Gable. I presently reside at 4501 Stonecrest Terrace, St. Joseph, Missouri, 64506.

2. I received my Doctor of Veterinary Medicine ("DVM") degree from Ohio State University in 1960. My list of professional qualifications is attached as Exhibit 1.

3. I am currently working as an independent contractor in the position of Consultant in Pharmaceutical Regulatory Affairs, and as a sub-contractor in the position of Senior Food and Drug Administration ("FDA") Regulatory Affairs Associate with Herschel J. Gaddy & Associates in St. Joseph, Missouri. I have been retained in my independent contractor capacity by Pennfield Oil Company/Pennfield Animal Health (collectively "Pennfield") and their legal counsel, Buchanan Ingersoll P.C., to provide my expert opinion in this matter because of my expertise in FDA/Center for Veterinary Medicine ("CVM") animal drug regulatory matters, including the history of the new animal drug approval ("NADA") process.

4. I have been employed as both a Consultant and Senior FDA Regulatory Affairs Associate since 2000. As an independent contractor working as a Consultant, I provide consulting services and compliance strategies for the preparation, compilation, and filing of, as well as follow-up on, various human and animal drug submission documents. I also provide consultation and preparation services for animal testing protocols for studies, and I provide assistance on understanding the animal drug regulations, as well as FDA/CVM policies and procedures.

5. Prior to my work as a Consultant, I was employed at Boehringer Ingelheim Vetmedica, Inc. ("BIV") from 1996 to 2000 as Manager of Pharmaceutical Regulatory Affairs. In this position, I was responsible for managing the registration of animal drug products, including new chemical entities, for approval and marketing worldwide. I also was involved in the global registration of products that had been previously manufactured by my former employer, Fermenta Animal Health Company ("Fermenta"). In December 1995 Fermenta was sold to BIV.

6. Prior to my employment at BIV, I was employed at Fermenta from 1991 to 1996 as the Director of Special Projects in Regulatory Affairs. While at Fermenta, I was involved in the preparation of NADAs for submission to FDA and the preparation of applications for submission to foreign countries as well. I was also involved in all stages of animal drug safety and efficacy studies. Finally, I provided expertise in the regulation of animal drugs in the United States and Canada and evaluated regulation requirements in other countries as well.

7. Prior to my employment at Fermenta, I was employed at CVM within FDA from 1965 to 1991 in numerous capacities, including most recently (1983-1991) as the Director of the Division of Therapeutic Drugs for Food Animals. Of particular relevance to this declaration is the fact that I was employed as a Staff Officer in the Office of the Center Director from 1968-1971, where I was intimately involved in the organization and execution of the Drug Efficacy Study Implementation ("DESI") review process.

8. Prior to serving in the Office of the Center Director at CVM from 1996-1968, I was responsible for organizing the The National Academy of Sciences/National Research Council ("NAS/NRC") review process, including deciding upon the twelve categories of active drug ingredients to be reviewed, which together comprised more than 700 NADAs and certifiable antibiotic submissions then on the market. These products were on the market on the grounds that they were covered by an NADA, a new drug application ("NDA"), a master file, an antibiotic regulation, or a food additive regulation, or they were exempt from regulation on grounds that they were generally recognized as safe ("GRAS"). It was not until the enactment of the Animal Drug Amendments of 1968 ("1968 Amendments") that § 512 was added to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), which codified approvals for animal drugs that had been granted by the above-listed mechanisms and which provided for the modern-day NADA approval process.

9. The NAS/NRC review process was initiated as a direct result of the passage of the 1962 Kefauver-Harris Drug Amendments ("1962 Amendments"). While prior to passage of the 1962 Amendments only safety data was required for human and animal drugs, after the passage of these Amendments both safety and efficacy data were required to be presented. The NAS/NRC/DESI review process was intended to provide efficacy reviews of active drug ingredients for drug products already on the market, but which prior to their marketing had been evaluated for safety only. NAS/NRC aided FDA in the conduct of this efficacy review process, beginning in 1966. The labeling of animal drug products at that time contained broad claims and often addressed merely the major species. The NAS/NRC/DESI review process was a review process of these broad claims and species, and those claims and species have subsequently been refined as animal husbandry practices have become more sophisticated.

10. Before the NAS/NRC review process, CVM requested information from manufacturers of drug products already on the market, as well as other interested parties. In addition, scientific literature was reviewed and information from FDA's files was utilized by the expert reviewers. On the basis of this agglomeration of information, NAS/NRC made findings and subsequent recommendations to CVM based on these findings. Both NAS/NRC reviewers and FDA reviewers relied upon their own expertise during the review process, and as discussed in the NAS/NRC/CVM contract, the expertise of the scientists was a primary criterion in the decision making process.

11. FDA published the NAS/NRC's findings in the Federal Register ("FR"). I was involved in the publication process of these findings. Furthermore, I was part of a group that used the NAS/NRC/DESI review findings, along with our expertise, to determine which

claims sponsors could make on their labels. Claims that were sanctioned based on the NAS/NRC findings were applied identically for every applicant whose drug product contained a given active drug ingredient. After the DESI findings were publiched in the FR one of the preclearance review divisions at CVM met with sponsors on the content of the labeling.

12. Furthermore, between 1971 and 1976 I was employed as an Assistant to the Director in the Division of Nutritional Sciences, where I was responsible for evaluating NADAs relating to the production uses of drug products.

13. Intermittently I was still involved in discussions with NAS/NRC because the DESI review process was still ongoing; in fact, decades after the DESI review process began, it is still not completed. Over the past decade, I have observed CVM's actions with regard to numerous animal drug products covered by the DESI review for which no finalization and withdrawal of approval of the claims not supported by substantial evidence of effectiveness had been completed. Many of these drugs and drug products utilized broad claims and species. Ultimately, narrower, more refined claims were subsumed within these broad claims.

14. As a result of my employment history and familiarity with the DESI review process, I am familiar with the requirements of the NADA approval process, and I understand that data showing a drug product is both safe and effective must now be provided in an NADA. I am also familiar with the requirements for filing a supplemental NADA.

15. Based on my experience, DESI review findings were applied to all drug products approved under the FFDCA, as amended, as well as to all identical, related, or similar drug products. As such, the data reviewed by NAS/NRC and CVM were considered as a whole, and included published data, data submitted by drug sponsors, revisions in labeling, and Agency expertise. Individual pieces of data, regardless of when they were provided, were not segregable from the whole body of data that established safety and effectiveness of the active drug ingredients and drug products.

16. To the best of my knowledge, recollection, and experience, DESI review findings of less than effective were upgraded to effective by FDA based on labeling revisions, published data, expert opinion, field investigations, and subsequent submissions, among other factors. This "hybrid" of data would thus support DESI upgrades of claims.

17. As noted in a seminal reference on CVM DESI activity, Compendium of Veterinary Drug Efficacy by Shotwell and Carr, the NAS/NRC findings are accepted by FDA to support the correctness of dosage and appropriateness of label claims for any given drug. Exhibit 2. Because the NAS/NRC evaluation is public information, its incorporation into applications for FDA premarket approval removes most normal requirements for detailed data supporting effectiveness as well as safety to the species to be treated. This procedure has resulted in significant economic savings to generic drug manufacturers and has relieved FDA of the necessity of reviews of data to support registration of those drugs which were evaluated by the NAS/NRC and found effective and *probably effective.*

18. Furthermore, it was historic FDA policy and precedent to apply "hybrid" data to classes of products, especially antibiotics originally marketed under FFDCA § 507, the antibiotic public rule. Under § 507, data required batch certification of drug products containing certain antibiotics. Generic versions of these antibiotics needed only to file Forms 6, now termed Abbreviated Antibiotic Drug Applications, which contained only manufacturing data, and many uses in animal feed were exempted totally from even the requirement. Many animal drug products were also exempted from this batch certification process. The antibiotic public rule functioned as a monograph and general rule, with safety and effectiveness data applicable to all identical, related, or similar drug products and those drug products exempt from the rule. The application of the DESI review process did not change how the rule was applied to these products and their claims. After enactment of the Animal Drug Amendments of 1968, which conveyed legal approval to these drug products, the same procedures and principles were applied to drugs previously marketed.

19. At the time the 1962 Amendments were enacted, animal drug claims were often broad and, once the DESI review findings (including labeling requirements) were made, such findings were applicable to all holders of legal animal drug product approvals. FDA has historically considered, as its best public policy, that congruent labeling of pioneer and generic drug products as well as of identical, related, or similar drug products should exist. This policy was followed, for example, in CVM's procedures to regulate intramammary infusion products, sulfonamides, and others. CVM reiterated this policy position in its third policy letter following the passage of the Generic Animal Drug and Patent Term Restoration Act ("GADPTRA") which would permit the pioneer sponsor to copy a generic innovation without submission of additional data. CVM believes that these interpretations would meet important goals of the generic legislation: "to avoid duplicative research, to provide incentive for generic sponsors to innovate, and to make the conditions of use of the pioneer and generic drugs the same to the maximum extent possible." The desire to have congruent labeling exists especially when multiple companies and experts generated data, and that data was evaluated with the Agency's expertise.

20. In my capacity at CVM, I became familiar with the promulgation of 21 C.F.R. §§ 558.15 and 558.15(g). The promulgation of both 21 C.F.R. § 558.15 and § 558.15(g) involved notice-and-comment rulemaking, and the Agency considered which companies held legal approvals for various animal drug products. One key reason why rulemaking was chosen was to obtain the input of the public and to provide clear public notice about the legal status of drug products then on the market and eligible for marketing. This is one function of FFDCA § 512(i): to provide public notice of approvals.

21. 21 C.F.R. § 558.15 was originally conceived by the Agency as an "interim" marketing regulation in an attempt to bring order to, and legitimize the marketing of, all the products marketed at that time under the 1968 Amendments and to all identical, related, or similar drug products whose sponsors filed commitments to do additional work on the drugs. CVM did this because, at that time, a large number of products were being marketed without any Agency knowledge or regulation. However, a court ruling forced

the Center to adjust its proposal before finalization. As a result of the court case that is cited in the preamble to the final rule promulgating 21 C.F.R. § 558.15(g), the Agency allowed only those drugs that had approvals under the FFDCA to be listed in 21 C.F.R. § 558.15. The Agency had reviewed its records and information that the sponsors had supplied, and determined that the companies to be listed in 21 C.F.R. § 558.15(g) had legal new animal drug approvals. Therefore, those sponsors listed in 21 C.F.R. § 558.15(g) have the equivalent of a full legal approval for their listed drug product(s).

22. The notion that 21 C.F.R. § 558.15 provides an "interim" approval or regulation is inaccurate. That term is an historical artifact that is factually inaccurate but has carried over as Agency jargon. Between the time of the publication of the proposed and final rules promulgating 21 C.F.R. § 558.15(g) in the FR, the courts had rejected the concept of interim marketing.

23. As part of the 21 C.F.R. § 558.15 review process and for decades later, the data among all the submissions were cross-referenced and applied to applications for claims considered under the DESI review process, 21 C.F.R. §558.15, and others, *e.g.*, sulfonamides. This fact is particularly common when drugs were legally approved for major species (*e.g.*, swine, poultry, cattle) and refinements were subsequently made.

24. I am familiar with GADPTRA and the fact that CVM issued nine policy letters following the passage of GADPTRA. I was a member of the Generic Animal Drug Committee that drafted the first eight policy letters. These policy letters were drafted in order to interpret the provisions of GADPTRA as that law would be applied by CVM.

25. Under GADPTRA, applications for generic animal drug products (abbreviated new animal drug applications, "ANADAs") are approved on the basis of findings of safety and effectiveness from "pioneer" animal drug applications, on the application of publicly available data, and on the scientific literature, among other factors. GADPTRA also provided that, in certain circumstances, supplements that were filed would receive three years of exclusivity if unique data were supplied for indications approved after 1988. In other cases, or if any applicable three year period has expired, data in those applications would be available to be relied upon by other applicants.

26. GADPTRA and the nine policy letters issued by CVM are consistent with CVM's historic policies of treating antibiotics generally as a class. Like human drug products, animal drug products that were approved followed a similar broad approach to the utilization of data, including the application to all species, uses, and indications. DESI review data that applied to the upgrading of claims or finalization came from a variety of sources.

27. Through the DESI review process and subsequent to enactment of GADPTRA, applications were approved in a variety of ways, including through the reliance upon safety and effectiveness data from other sources in order to show that two drug products are equivalent. Such applications are now recognized as "hybrid" NADAs. One of the functions of such applications is to provide consistent, identical labeling.

28. I am familiar with the Animal Drug Availability Act of 1996 ("ADAA") and its changes to the definition of the term "substantial evidence" as it relates to proving the effectiveness of a new animal drug product. Prior to enactment of ADAA, the statutory term was defined as evidence from adequate and well-controlled investigations, including field studies. Since 1996 substantial evidence is now expanded and made more flexible per 21 C.F.R. § 514.4, to include studies such as a study in the target species, a study in laboratory animals, field study, *in vitro* study, and other studies on which basis qualified experts could reasonably conclude that the drug will have the effect that it purports to have in its labeling, and the studies were performed by qualified experts, are repeatable, that the responses reliably reflect effectiveness, and that valid inferences can be drawn to the target population. The flexibility is described in the rulemaking procedure, 62 Fed.Reg. 59830, 64 Fed.Reg. 40746.

29. For all the major species (*e.g.,* swine, poultry, cattle), CVM has concluded that bacitracin MD is effective, *i.e.,* substantial evidence of effectiveness exists. For refinements and revisions in the approved existing claims whose approvals have never been withdrawn, CVM has stated that substantial evidence as now refined by the ADAA exists. This statutory term is now far broader and more flexible than that term was previously used, as shown in 21 C.F.R. § 514.4 and the preambles in the rulemaking process. Such evidence can be used to extrapolate among claims and species. Thus, existing evidence can be used for refinements and revisions in labeling claims.

30. I know that Pennfield Oil Company/Pennfield Animal Health (collectively "Pennfield") is the current owner of the application now known as NADA 141-137 for a bacitracin methylene disalicylate ("bacitracin MD") product which the company is currently marketing as Pennitracin MD 50-G™ ("Pennitracin") (Exhibit 3). Because of my prior employment at BIV and Fermenta, I know that BIV is Pennfield's immediate predecessor in interest with respect to this application, and BIV's immediate predecessor in interest is Fermenta. Prior to Fermenta's interest in the application, I know that SDS Biotech ("SDS") held interest in the application, and Diamond Shamrock Chemical Corp. ("Diamond") is SDS's predecessor in interest for this application. Prior to the enactment of the 1968 Amendments, bacitracin was marketed under an Antibiotic Form 6 and most of the antibiotics used in animal feed such as bacitracin MD were ultimately exempted from batch certification under § 507, and thus it was approved under the transition provisions of the Animal Drug Amendments of 1968. Diamond subsequently filed what was known at that time as master file ("MF") 3577 for administrative convenience, in my view. MF 3577 was officially recognized as approved for Noptracin® MD-50 Type A Medicated Article on February 25, 1974.

31. It is not clear that CVM has fully recognized the impact of the ADAA in changing the applicability of certain DESI findings. CVM did not discuss this impact on DESI findings in either the FR notices that promulgated FDA's regulations on "substantial evidence" under the ADAA, or in the August 8, 2003 FR notice of opportunity for hearing ("NOOH") which prompted this request for hearing by Pennfield.

32. Pennfield's approval is incorrectly listed in 21 C.F.R. § 558.15(g)(1) (2003)

under the name of Fermenta, one of the prior owners of the relevant application. Section 558.15(g)(1) lists Fermenta as having approval for a Type A bacitracin MD article for chickens, turkeys, swine, and cattle for the use levels and indications for use listed in the cross-referenced section 21 C.F.R. § 558.76. Furthermore, 21 C.F.R. § 558.76(d)(1)(i) and (ii) list the four claims that were approved under the DESI review process, covering chickens, turkeys, pheasants, and quail. The DESI review process for bacitracin MD considered claims for "poultry" and swine. "Poultry" includes chickens, turkeys, pheasants, and quail. I have also reviewed the Stipulation and Order of Dismissal ("Stipulation") in the case of Alpharma, Inc. v. McClellan (2003) and I am aware that the parties to that Stipulation have agreed that Pennfield is entitled to make claims for cattle (Exhibit 4). Therefore, Pennfield is entitled to make claims for the species chickens, turkeys, pheasants, quail, swine, and cattle. As such, CVM has concluded that substantial evidence of effectiveness exists for all these major species.

33. During my employment at BIV, I recognized the fact that FDA had confused the marketplace, and had continued to use confusing factually and legally imprecise language such as "interim marketing," post DESI, and DESI finalization. CVM's continued use of this language obscured approval for historic claims and longstanding policies. To clarify my understanding of the issues, I sent a letter to Dr. Andrew Beaulieu, Acting Director of the Office of New Animal Drug Evaluation, dated July 16, 1998 (Exhibit 5). In that letter, I asked "what are the current labeling claims for the interim marketed Bacitracin Methylene Disalicylate Type A Medicated Article: (1) claims prior to DESI finalization, (2) claims reflecting DESI finalization or (3) claims currently codified in 21 C.F.R. 558.76 and 21 C.F.R. 510.515?" To the best of my knowledge and recollection, neither Dr. Beaulieu nor anyone else at FDA provided a response regarding my labeling questions.

34. During my employment at BIV, I received a letter from Dr. Stephen F. Sundlof, Director of the Center for Veterinary Medicine, dated July 29, 1998 (Exhibit 6). This letter outlined the purpose of 21 C.F.R. § 558.15, and stated that "the Agency intended to include in the 21 C.F.R. § 558.15 listings only new animal drugs or combinations of new animal drugs and conditions of use approved by one of the mechanisms described above [new animal drug application, new drug application, master file, antibiotic regulation, or food additive regulation]." However, this same letter also indicated that FDA was "unable to reconstruct from its records the existence of an approval for" BIV's bacitracin MD product. Therefore, the Agency asked "that such sponsors, if they have information...establishing that an approval corresponding to a specific listing in section 558.15 was granted prior to the February 25, 1976, publication date of 21 C.F.R. § 558.15, identify the involved product(s) and certify the approval status to the Agency."

35. It appears to me that this sponsor certification process was directed at informally undoing what had already been accomplished by the promulgation of 21 C.F.R. § 558.15(g), namely that those sponsors listed in 21 C.F.R. § 558.15(g) were being asked to certify that they were entitled to be listed in that section when such a determination had already been made via the public rulemaking process.

36. In response to Dr. Sundlof's July 29, 1998 letter, I submitted a letter dated September 18, 1998 to Dr. Sundlof (Exhibit 7). In that letter I outlined the extensive history of BIV's bacitracin MD product, including information from BIV's predecessors in interest. I attached to that letter numerous pieces of correspondence and other documents reconfirming that BIV was entitled to be listed in 21 C.F.R. § 558.15 as a sponsor of a bacitracin MD product as of February 25, 1976. I also included in that September 18, 1998 letter a product label, dated February 1969, for Noptracin® MD-50 Antibiotic Feed Supplement for Nopco Feed Supplements Department, Biochemicals Division, Diamond Shamrock Chemical Company. I included this February 1969 label as a means of tracing the history of this product back to the 1960's and to demonstrate that one of BIV's predecessors in interest for this application had been marketing the product prior to February 25, 1976 and even before 1968.

37. Furthermore, on November 17, 1998 I submitted to Dr. Sundlof an amendment to my September 18, 1998 letter (Exhibit 8). This November 17, 1998 letter did not contain any attached labels but did again, in brief fashion, trace the regulatory status of this product.

38. Under FDA's regulations (21 C.F.R. § 10.70, 21 C.F.R. Part 514) all these submissions were required to be contained in CVM's administrative files for these applications.

39. Following my submission of the September 18, 1998 and November 17, 1998 certification letters to FDA, I spoke with individuals in CVM regarding labeling and approvals. To the best of my knowledge and recollection, on December 9, 1998 I received a phone call from Dr. Dianne T. McRae of the Generic Animal Drug and Quality Control Staff in the Office of New Animal Drug Evaluation. Dr. McRae asked that I provide her with "labels" for bacitracin MD as a final step for reconfirming the established approval of our bacitracin MD product that I had confirmed in my September 18, 1998 and November 17, 1998 certification letters.

40. In my long experience, submission of labeling in response to telephone calls and last minute correspondence is a normal procedure for finalizing or recognizing approval of an animal drug application.

41. On December 9, 1998 I sent a three-page fax to Dr. McRae (Exhibit 9). In addition to the cover page, I submitted two labels for bacitracin MD: (1) one label including claims for swine, cattle, chickens, turkeys, pheasants, and quail, and (2) one label including claims for only swine, cattle, and chickens (no minor species included). On the fax cover sheet appear my handwritten notes describing the attached labels.

42. Subsequent to my fax of these two labels to Dr. McRae on December 9, 1998, I received from Dr. Sundlof a letter dated December 17, 1998 that confirmed receipt of the September 18, 1998 and November 17, 1998 certification letters (Exhibit 10). The December 17, 1998 letter states, in relevant part, "[i]n accordance with my letter, your certification will be used along with information in our files as the administrative record of an approval for NADA 141-137, which provides for a Type A Medicated Article, Noptracin® MD-50 (bacitracin methylene disalicylate) for use for the indications and

Declaration of Andrew L. Winstrom
In Support of Pennfield Oil Company/Pennfield Animal Health's
Request for Hearing re: NADA 141-137 (Pennitracin MD 50-G™)

Docket No. 2003N-0324

1. My name is Andrew L. Winstrom. I presently reside at 14040 Industrial Road, Omaha, Nebraska.

2. I am currently employed as the President of Pennfield Animal Health in Omaha, Nebraska.

3. I have been employed as President of Pennfield Animal Health since 1988. As President and Pennfield's largest stockholder, I act as manager of Pennfield Animal Health's affairs.

4. I know that Pennfield Oil Company/Pennfield Animal Health (collectively "Pennfield") is the current owner of the application known as new animal drug application ("NADA") 141-137 for a bacitracin methylene disalicylate ("bacitracin MD") product the company currently markets as Pennitracin MD 50-G™ ("Pennitracin") (Exhibit 1). I also know that Pennfield bought this application from Boehringer Ingelheim Vetmedica, Inc. ("BIV") in 2002. FDA was made aware of the sale of this application by letter dated August 19, 2002 from Gregory P. Bergt, Director of Research & Development at Pennfield Oil Company, to Dr. Stephen F. Sundlof, Center Director of the Center for Veterinary Medicine ("CVM") (Exhibit 2). Furthermore, on October 3, 2002 Mr. Bergt received a letter from Lonnie Luther, Chief of the Generic Drug Animal Team at the Office of New Animal Drug Evaluation at CVM. Dr. Luther's October 3, 2002 letter acknowledges receipt of this August 19, 2002 letter regarding the acceptance of ownership of NADA 141-137 from BIV (Exhibit 3).

5. Pennfield's approval is incorrectly listed in 21 C.F.R. § 558.15(g)(1) (2003) under the name of Fermenta Animal Health Co. ("Fermenta"), a predecessor in interest to BIV for this application.

6. Based on discussions that took place between Pennfield and BIV prior to Pennfield's 2002 purchase of this application, I was made aware of the certification process that had taken place in 1998 and the written and oral correspondences between CVM and BIV that were generated as part of that process. The content of those certification correspondences, as represented to me by BIV, showed that BIV had lawful approval for all the claims, species, and indications for use listed in 21 C.F.R. § 558.15 as cross-referenced in § 558.76.

7. As part of these purchase discussions, I became aware of a March 12, 2002 letter sent from Donald A. Buss, Director of Regulatory Affairs at BIV to Andrew J. Beaulieu, Associate Director for Animal Health Policy and Regulation at CVM requesting a meeting regarding the status of NADA 141-137 (Exhibit 4). This letter states that BIV's bacitracin MD product (Noptracin® MD 50) is labeled for use in growing/finishing swine, pregnant sows, feedlot beef cattle, broiler chickens, laying hens, growing turkeys, pheasants, and quail. Included with this letter is a label that is congruent with the label Pennfield is currently using as the labeling on its Pennitracin product.

Declaration of Andrew L. Winstrom Re: NADA 141-137

Confidential Commercial and/or
Trade Secret Documents Redacted:

Exhibit 1	Pennfield Animal Health Product Information Label for Pennitracin MD 50-G™ Bacitracin Methylene Disalicylate.
Exhibit 2	Letter from Gregory P. Bergt, Pennfield Oil Co. to Stephen Sundlof, FDA, dated Aug. 12, 2002.
Exhibit 3	Letter from Lonnie W. Luther, CVM to Gregory P. Bergt, Pennfield Oil Co., dated Oct. 3, 2002.
Exhibit 4	Boehringer Ingelheim Vetmedica Request for Meeting re: NADA 141-137, Nortracin® MD 50 - Bacitracin Methylene Disalicylate, dated Mar. 12, 2002 (with attachments).
Exhibit 5	Boehringer Ingelheim Vetmedica Conference Notes of Meeting Between Boehringer Ingelheim Vetmedica, Pennfield Animal Health, and FDA/CVM re: Noptracin MD 50, held May 1, 2002.